Hall et al.

Application No.: 09/441,966 Filed: November 17, 1999

Page 2

Atty. Docket No.: AERO1120-1

Patent

Amendments to the Claims

Please amend claims 1, 16 and 23 as indicated in the listing of claims.

Please cancel claims 15, 17 and 19 without prejudice.

Claims 11-14 and 22 were previously canceled.

Claims 18 and 20-21 were previously withdrawn.

The listing of claims will replace all prior versions, and listings of claims in the application.

Listing of Claims:

- 1. (Currently amended) A method for accelerating the rate of mucociliary clearance in a subject in need thereof, comprising administering to the subject an effective mucociliary clearance stimulatory amount of a composition comprising a human Kunitz-type serine protease inhibitor and a physiologically acceptable carrier, wherein the human Kunitz-type serine protease inhibitor is SEQ ID NO:8, and wherein the effective amount is at least about 9 mg, thereby accelerating the rate of mucociliary clearance.
- 2. (Previously presented) The method according to claim 1, wherein the composition is administered to the lung airways.
- 3. (Previously presented) The method according to claim 1, wherein said composition is administered directly by aerosolization.
- 4. (Previously presented) The method according to claim 1, wherein said composition is administered directly as an aerosol solution into the subject's respiratory tract.
- 5. (Previously presented) The method according to claim 4, wherein said aerosol solution includes respirable particles ranging in size from about 1 to about 10 microns.

Hall et al.

141,966

Application No.: 09/441,966 Filed: November 17, 1999

Page 3

6. (Previously presented) The method according to claim 4, wherein said aerosol solution includes respirable particles ranging in size from about 1 to about 5 microns.

Patent

Atty. Docket No.: AERO1120-1

- 7. (Previously presented) The method according to claim 4, wherein said aerosol solution is delivered to said subject by a pressure driven nebulizer or administered as dry powder.
- 8. (Previously presented) The method according to claim 4, wherein said aerosol solution is delivered to said subject by an ultrasonic nebulizer.
- 9. (Previously presented) The method according to claim 4, wherein said aerosol solution is delivered to said subject by a non-toxic propellant.
- 10. (Previously presented) The method to claim 1, wherein said carrier is a member selected from the group consisting of a physiologically buffered solution, an isotonic saline, normal saline, and combinations thereof.
 - 11-14. (Canceled).
 - 15. (Canceled).
- 16. (Currently amended) The method according to claim 1-or-15, wherein the human Kunitz-type serine protease inhibitor is glycosylated.
 - 17. (Canceled).
- 18. (Withdrawn) The method according to claim 1, wherein the Kunitz-type serine protease inhibitor contains at least one intra-chain cysteine-cysteine disulfide bond selected from

Hall et al.

Atty. Docket No.: AERO1120-1

Patent

Application No.: 09/441,966 Filed: November 17, 1999

Page 4

the cysteine-cysteine paired groups consisting of CYS11-CYS61, CYS20-CYS44, CYS36-CYS57, CYS106-CYS156, CYS115-CYS139, and CYS131-CYS152 for any of SEQ ID NO.: 49, SEQ ID NO.: 2, SEQ ID NO.: 45, SEQ ID NO.: 47, SEQ ID NO.: 71, SEQ ID NO.: 70, SEQ ID NO.: 3, SEQ ID NO.: 50, SEQ ID NO.: 1, and SEQ ID NO.: 52, wherein the cysteine residues are numbered according to the amino acid sequence of SEQ ID NO.: 52.

19. (Canceled).

- 20. (Withdrawn) The method according to claim 1, wherein the Kunitz-type serine protease inhibitor contains at least one intra-chain cysteine-cysteine disulfide bond selected from the cysteine-cysteine paired groups consisting of CYS106-CYS156, CYS115-CYS139, and CYS131-CYS152 for any of SEQ ID NO.: 6, and SEQ ID NO.: 7, wherein the cysteine residues are numbered according to the amino acid sequence of SEQ ID NO.: 52.
- 21. (Withdrawn) The method according to claim 1, wherein the human Kunitz-type serine protease inhibitor contains at least one intra-chain cysteine-cysteine disulfide bond selected from the cysteine-cysteine paired groups consisting of CYS11-CYS61, CYS20-CYS44, CYS36-CYS57, wherein the cysteine residues are numbered according to the amino acid sequence of SEQ ID NO.: 52.

22. (Canceled).

- 23. (Currently amended) The method of claim 1, wherein the Kunitz-type serine protease inhibitor inhibits a sodium channels channel.
- 24. (Previously presented) The method of claim 23, wherein the channel is an epithelial sodium channel.

Hall et al.

Application No.: 09/441,966

Filed: November 17, 1999

Page 5

25. (Previously presented) The method of claim 1, wherein Kunitz-type serine protease increases tracheal mucus velocity (TMV) in the subject.

Patent

Atty. Docket No.: AERO1120-1